

**APPLICATION FOR
UNITED STATES LETTERS PATENT**

Be it known that we, ROBERT M. JUDD of 1062 Kingsport Drive, Wheeling, Illinois 60090; ENN-LING CHEN of 57 East Delaware Place, Unit 1601, Chicago, Illinois 60611 and Raymond J. Kim of 57 East Delaware Place, Unit 1601, Chicago, Illinois 60611, have invented a new and useful "MEDICAL IMAGE MANAGEMENT SYSTEM."

TITLE**MEDICAL IMAGE MANAGEMENT SYSTEM****FIELD OF THE INVENTION**

5 The present invention relates to medical imaging. Specific exemplary embodiments discussed relate to cardiac medical imaging.

BACKGROUND OF THE INVENTION

10 The description of art in this section is not intended to constitute an admission that any patent, publication or other information referred to herein is "prior art" with respect to this invention, unless specifically designated as such.

15 Medical imaging is important and widespread in the diagnosis of disease. In certain situations, however, the particular manner in which the images are made available to physicians and their patients introduces obstacles to timely and accurate diagnosis of disease. These obstacles generally relate to the fact that each manufacturer of a medical imaging system uses different and proprietary formats to store the images in digital form. This means, for example, that images from a scanner manufactured
20 by General Electric Corp. are stored in a different digital format compared to images from a scanner manufactured by Siemens Medical Systems. Further, images from different imaging modalities such as ultrasound and MRI are stored in formats different from each other. Although it is typically possible to "export" the images from a proprietary workstation to
25 an industry-standard format such as "Digital Imaging Communications in Medicine" (DICOM) 3.0, several limitations remain as discussed subsequently. In practice, viewing of medical images typically requires a

different proprietary "workstation" for each manufacturer and for each modality.

Currently, when a patient describes symptoms the patient's primary physician often orders an imaging-based test to diagnose or assess disease.

5 Typically days after the imaging procedure, the patient's primary physician receives a written report generated by a specialist physician who has interpreted the images. The specialist physician, however, typically has not performed a clinical history and physical examination of the patient and often is not aware of the patient's other test results. Conversely, the
10 patient's primary physician typically does not view the images directly but rather makes a treatment decision based entirely on written reports generated by one or more specialist physicians. Although this approach does allow for expert interpretation of the images by the specialist physician, several limitations are introduced for the primary physician and
15 for the patient:

- 1) the primary physician does not see the images unless he/she travels to another department and makes a request;
- 2) it is often difficult to find the images for viewing because there typically is no formal procedure to accommodate requests to show
20 the images to the primary physician;
- 3) until the written report is forwarded to the primary physician's office, it is often difficult to determine if the images have been interpreted and the report generated;
- 4) each proprietary workstation requires training in how to use the
25 software to view the images;

- 5) it is often difficult for the primary physician to find a technician who has been trained to view the images on the proprietary workstation;
- 6) the workstation software is often "upgraded" requiring additional training;
- 7) the primary physician has to walk to different departments to view images from the same patient but different modalities;
- 8) images from the same patient but different modalities cannot be viewed side-by-side, even using proprietary workstations;
- 9) the primary physician cannot show the patient his/her images in the physician's office while explaining the diagnosis; and
- 10) the patient cannot transport his/her images to another physician's office for a second opinion.

It would be desirable to allow digital medical images to be viewed by multiple individuals at multiple geographic locations without loss of diagnostic information.

"Teleradiology" allows images from multiple scanners located at distant sites to be transferred to a central location for interpretation and generation of a written report. This model allows expert interpreters at a single location to examine images from multiple distant geographic locations. Teleradiology does not, however, allow for the examination of the images from any site other than the central location, precluding examination of the images by the primary physician and the patient. Rather, the primary physician and the patient see only the written report generated by the interpreters who examined the images at the central location. In addition, this approach is based on specialized "workstations" (which require substantial training to operate) to send the images to the

central location and to view the images at the central location. It would be advantageous to allow the primary physician and the patient to view the images at other locations, such as the primary physician's office, at the same time he/she and the patient see the written report and without
5 specialized hardware or software.

In principle, medical images could be converted to Internet web pages for widespread viewing. Several technical limitations of current Internet standards, however, create a situation where straightforward processing of the image data results in images which transfer across the Internet too
10 slowly, lose diagnostic information, or both. One such limitation is the bandwidth of current Internet connections which, because of the large size of medical images, result in transfer times which are unacceptably long. The problem of bandwidth can be addressed by compressing the image data before transfer, but compression typically involves loss of diagnostic
15 information. In addition, due to the size of the images the time required to process image data from an original format to a format which can be viewed by Internet browsers is considerable, meaning that systems designed to create web pages "on the fly" introduce a delay of seconds to minutes while the person requesting to view the images waits for the data to be processed.
20 Workstations allow images to be reordered or placed "side-by-side" for viewing but again an Internet system would have to create new web pages "on the fly" which would introduce further delays. Finally, diagnostic interpretation of medical images requires the images are presented with appropriate brightness and contrast. On proprietary workstations these
25 parameters can be adjusted by the person viewing the images but control of image brightness and contrast are not features of current Internet standards (http or html).

It is possible to allow browsers to adjust image brightness and contrast, as well as other parameters, using "Java" programming. "Java" is a computer language developed by Sun Microsystems specifically to allow programs to be downloaded from a server to a client's browser to perform certain tasks. Using the "Java" model, the client is no longer simply using the browser to view "static" files downloaded from the server, but rather in addition the client's computer is running a program that was sent from the server. There are several disadvantages to using "Java" to manipulate the image data. First, the user must wait additional time while the "Java" code is downloaded. For medical images the "Java" code is extensive and download times are long. Second, the user must train to become familiar with the controls defined by the "Java" programmer. Third, the user must wait while the "Java" code processes the image data, which is slow because the image files are large. Fourth, "Java" code is relatively new and often causes browsers to "crash". Finally, due to the "crashing" problem "Java" programmers typically only test their code on certain browsers and computers, such as Microsoft Explorer on a PC, precluding widespread use by owners of other browsers and other computer platforms.

Wood et al. (US005891035) describe an ultrasound system which incorporates an http server for viewing ultrasound images over the Internet. The approach of Wood et al., however, creates web pages "on the fly" meaning that the user must wait for the image processing to complete. In addition, even after processing of the image data into a web page the approach of Wood et al. does not provide for processing the images in such as way that excessive image transfer times due to limited bandwidth are addressed or provide for "brightness/contrast" to be addressed without loss of diagnostic information. In addition, the approach of Wood et al. is

limited to ultrasound images generated by scanners manufactured by a single company (ATL), and does not enable viewing of images from modalities other than ultrasound.

Fig. 1 summarizes a common prior art approach currently used by companies to serve medical images to Internet browsers (e.g. General Electric's "Web-Link" component of their workstation-based "Picture Archiving and Communication System" (PACS)). As can be seen in Fig. 1, serial processing of image data "on the fly" combined with extensive user interaction results in a slow, expensive, and unstable system.

Referring to Fig. 1, after a scanner acquires images (Step 100) a user may request single image as a webpage (Step 200) whereby the image data is downloaded (Step 300) to allow the user to view a single image with the single image (Step 400). Steps 1000-1400 result in extensive user interaction which results in the system being slow, expensive and unstable.

While the present invention relates to medical imaging generally, it will be better understood within the discussion of exemplary embodiments directed toward cardiac imaging.

SUMMARY OF THE INVENTION

The current invention proceeds from the realization that if medical images of different formats could be processed in such a way that limitations of current Internet standards could be overcome, any standard Internet browser could be used as a diagnostic workstation to allow any medical image to be viewed from any location on earth without specialized hardware or software. Once this goal has been achieved the following actions becomes possible:

- 1) to notify the primary physician via e-mail or pager as soon as the imaging has been completed;
- 2) for the primary physician to view the images with a single "double click";
- 5 3) to view the images at the same time the primary physician and/or the patient reads the written report;
- 4) to view images of the same patient but from different modalities side-by-side;
- 5) to view images of the same patient and same modality but
10 different time points side-by-side to assess the progression of disease;
- 6) for the primary physician to discuss the images over the telephone with another physician who is viewing the same images simultaneously at another location;
- 15 7) to make diagnoses and clinical treatment plans from anywhere in the world including the physician's home;
- 8) to discuss the images with the patient in the physician's office or over the telephone with the patient at home;
- 9) for the patient to present the images to another physician for a
20 second opinion;
- 10) for the patient to move to a different city/state/country and have the images "move" with him/her.

Furthermore, once the standard Internet browser can be used as a diagnostic workstation it becomes feasible to construct a world-wide
25 database of medical images using a predefined hierarchical Internet addressing structure. This structure would allow for the unique address of all medical images for all persons throughout their lifetime.

Accordingly, one embodiment of the invention is directed toward a method of managing medical images. A plurality of medical images created by a plurality of medical imaging devices, each of which processes the medical image using a unique image format, is received. The medical
5 images are then converted to a common image format suitable for display on a computer screen. Preferably the method comprises posting the converted images for access via a client computer. Browser compatible pages having embedded tags corresponding to the converted images are preferably generated and posted with the converted images.

10 Another embodiment of the invention is directed towards a medical image database comprising images corresponding to a plurality of different modalities. The database is preferably organized in a hierarchical data structure where the data structure comprises a patient identifier parameter and an image modality identifier parameter. The image identifier
15 parameter is associated with at least one of the plurality of modalities. The patient identifier parameter is preferably at a higher level in the hierarchical data structure than the image modality identifier parameter.

In one method of managing medical images according to the present invention, images are pulled from a scanner in response to a user request.

20 The pulled images are converted to a common image format compatible for display at a computer. The converted images are then posted for display at a client computer. Preferably the method includes displaying to a user at the client computer a selection comprising images associated with at least two different modalities. The method also preferably comprises
25 simultaneously displaying on a screen a medical image to a first user at a first location and a second user at a second location.

A medical image system, according to the present invention, comprises a medical image management system. In a preferred embodiment the medical image management system comprises a transfer engine for receiving image data from a scanner; a converter engine
5 connected to receive images from the transfer engine and convert the images to a browser compatible format; and a post engine connected to receive images from the converter engine and post the images for subsequent access by a user.

In a preferred embodiment, the converter engine comprises a
10 decoding engine for extracting raw image data; and a physiologic knowledge engine adapted to receive data from the decoding engine. The physiologic knowledge engine adjusts the image quality and reduces the size of the image data, which is then transferred to a post engine. The physiologic knowledge engine is primarily responsible for reducing the image file size
15 without loss of diagnostic data though other aspects of the invention are used to reduce file size while maintaining viability of the data. The encoding engine converts the image data to browser compatible image data.

Other objects and advantages of the present invention will be apparent to those of skill in the art from the teachings herein.

BRIEF DESCRIPTION OF THE DRAWINGS

In the interest of enabling one of skill in the art to practice the invention, exemplary embodiments are shown and described. For clarity, details apparent to those of skill in the art and reproducible without undue
25 experimentation are generally omitted from the drawings and description.

Fig. 1 depicts a prior art method for user to view images from a scanner.

Fig. 2 depicts a block diagram of an imaging managing system according to an embodiment of the present invention.

Fig. 3 depicts a system overview of an embodiment of the present invention for providing a user with images from a scanner.

Fig. 4A depicts steps for affecting transfer of images from a scanner.

Fig. 4B depicts an alternate method for obtaining images from a scanner via a disk having the images stored thereon.

Fig. 5A depicts a method for extracting raw pixel data from a standard image data format.

Fig. 5B depicts a method for extracting raw pixel data from a non-standard image format.

Fig. 6 depicts a method for reducing image data files without loss of diagnostic data.

Fig. 7A describes a method for reducing image data file size without loss of diagnostic information.

Fig. 7B pictorially depicts selecting a bright pixel in a diagnostic search region.

Fig. 7C depicts the diagnostic search area in both representative thumbnail size and full screen size with corresponding file sizes indicated.

Fig. 8 depicts steps for converting the image to a browser compatible format.

Fig. 9 depicts a method for posting the browser compatible image to a database.

Fig. 10 is a diagram of a file structure for a web compatible database.

Fig. 11 depicts a possible interface structure for accessing web compatible database via the Internet.

Fig. 12 depicts a method for displaying an image stored on a web compatible database accessible via the Internet.

Fig. 13 depicts a selection of modalities for a patient, namely Doe, John.

5 Fig. 14 shows a image identification data obtained from a separate file displayed with the medical image.

Fig. 15 depicts a web page comprising ECG medical image data.

Fig. 16 depicts MRI medical image.

Fig. 17 depicts SPECT medical image data.

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DESCRIPTION OF EXEMPLARY EMBODIMENTS

The present invention is discussed in relation to imaging with specific applications discussed in relation to cardiac images, however, other uses will be apparent from the teachings disclosed herein. The present invention
15 will be better understood from the following detailed description of exemplary embodiments with reference to the attached drawings, wherein like reference numerals and characters refer to like parts, and by reference to the following claims.

The herein-described invention has been constructed and tested on
20 images of the heart acquired using a variety of modalities. The images have been pulled from commercial scanners, processed without loss of diagnostic information, adjusted with respect to brightness and contrast, and posted on Internet web pages for viewing.

Figs. 2 and 3 show the process in schematic form. In Fig. 2, a
25 medical image management system **10** is connected via a hospital intranet or the Internet **12** to a number of browsers **14** (such as Microsoft Explorer or Netscape Navigator). The connection **12** to the browsers is used to: 1)

accept commands to pull images from the scanners **16**; 2) to navigate through images which have already been posted as web pages; and 3) to arrange and organize images for viewing. The medical image management system **10** is also connected to a number of medical imaging systems (scanners) **16** via a hospital intranet or the Internet **12'**. The connection **12'** to the scanners **16** is used to pull the images by Internet-standard file transfer protocols (FTP). Alternatively, images can be transferred to the system **10** via a disk drive or disk **18** (see Figs. 2 and 3).

Preferably the scanner, and hence modality, is associated with magnetic resonance imaging, echocardiographic imaging, nuclear scintigraphic imaging (e.g., SPECT single photon emission computed tomography), positron emission tomography, x-ray imaging, and combinations thereof.

Responsibility for the entire process is divided amongst a series of software engines. The processes of the transfer engine **20**, decoding engine **22**, physiologic knowledge engine **24**, encoding engine **26**, and post engine **28** (Figs. 2 and 3) are preferably run automatically by computer and do not require the person using the browser, the user, to wait for completion of the associated tasks. The decoding engine **22**, physiologic knowledge engine **24**, and encoding engine **26** are, preferably, combined to form a converter engine. The post engine **28** sends an e-mail notification, via an e-mail server **30** (Fig. 2) to the person submitting the request when the computations are complete, thereby allowing the requester to do other tasks. Similarly, text messages could be sent to a physician's pager. The time necessary for these computations depends on the size of the images and the speed of the network, but was measured for the MRI images of Fig.

16 to be approximately 3 minutes over a standard ethernet 10BASET line (10 Mbps) using a 400 MHz computer.

The transfer engine **20** is responsible for pulling the images from the scanner **16** for example, in response to a user request (Step 2010). (Figs. 2 and 3, details in Fig. 4). Using previously recorded information such as username and password, (Step 2020) the transfer engine **20** logs into the scanner **16** over the Internet **12** (Step 2030) and pulls the appropriate images from the scanner **16** using standard Internet FTP or DICOM commands (Step 2040). Alternatively, images can be acquired by the transfer engine **20** by use of a disk drive **18** such as a CD-ROM (Figs. 2-4) (Steps 2011-2022). When the transfer process is complete, all images from the scan will exist within the transfer engine **20** but are still in their original digital format. This format may be specific to the scanner **16** manufacturer, or may be one of a variety of formats which are standard but cannot be displayed by browsers, such as DICOM. The images are then passed to the decoding engine (Step 3000).

The decoding engine **22** (Fig. 5) is responsible for extracting the raw image pixel data from the original, differing, non-web compatible digital formats that the transfer engine 20 acquired. In the case of standard formats such as DICOM, this can be accomplished by reading published file structures and writing computer code to read this format (Steps 3010-3020). In the case of non-standard formats, successful extraction of the image data proceeds from the realization that all formats differ from each other mainly in the header region of the image file, i.e., the part which contains information like the patient name, scan date, name of hospital, etc. (Steps 3011-3021.) Because the most important information such as patient name and scan date can be input via the web-based form pages

upon submission (see Figs. 14-17, for example), extraction of the image data for non-standard formats can be accomplished by ignoring the header data entirely and reading only the image data. Typically, the image data are stored as a series of pixel values starting at the upper left corner of the image and proceeding across each row of pixels from left to right and then repeating this process for all rows of the image (i.e. top to bottom).

The physiologic knowledge engine **24** (Fig. 6) is responsible for adjusting image brightness and contrast, adjusting image magnification, adjusting movie frame speed, and other image parameters important for diagnosis (Step 4010-4020). The physiologic knowledge engine **24** is also responsible for reducing the size of the images to allow acceptable transfer times at current Internet bandwidths without loss of diagnostic information (Step 4030). These tasks are achieved in part by the use of a priori knowledge of physiology, anatomy, the diagnostic question, or any combination of the three. One aspect of this is the realization that the human eye is capable of distinguishing less than 256 distinct levels of gray in a medical image, and that most of the field-of-view (FOV) of the image is not of diagnostic interest. The grayscale limitations of the human eye imply that any medical image can be compressed to 8-bits of grayscale levels and that, if appropriately scaled, the resulting image will have appropriate brightness/contrast without the need to adjust these using the web browser (Fig. 7A, Step 4020). This is important because adjustment of brightness/contrast by the browser is not part of existing Internet standards. Another important piece of a priori information is that much of the FOV is not of diagnostic interest. (Step 4030 and Fig. 7B) This implies that the images can be cropped which allows a significant reduction in the size of the image file. This is important because limitations of

existing Internet bandwidths result in excessive image transfer times if the file size is not reduced.

An example of how the physiologic knowledge engine **24** functions is given in Figs. 7A-7C for the specific case of MRI of the heart. In STEP 4020, the region of the image which contains the organ of diagnostic interest is defined (e.g. the heart). For the general case of a group of images which are intended to be played as a movie to depict time-varying quantities (e.g. heart motion), the physiologic knowledge engine **24** searches all movie frames for the single brightest pixel within the search region (e.g. within the heart). All pixels of all movie frames are then scaled such that the single brightest pixel within the search region of all frames equal 255 (e.g. 8-bit image). After this step, the image brightness/contrast are appropriate for the organ of interest without loss of diagnostic information.

In STEP 4030, thumbnail movies are extracted for which the FOV is reduced by cropping the images to contain only the organ of interest (e.g. the heart). For a typical file size of 2,000 KB for a movie with 16 frames, the processes herein described would result in a 20-fold reduction in movie file size for the thumbnails (to 100 KB) and 6-fold for full FOV images (to 400 KB). (See Fig. 7C.) These file sizes imply that every still-frame and every movie from an entire patient scan can be transferred over the Internet as thumbnails in a few seconds.

In STEP 4040, the frame rate is chosen to simulate real-time motion (e.g. a beating heart would have all frames play within one heart beat or about 1 second). In STEP 4050, full FOV images are created with a magnification which fills the user's entire screen because this is what a cardiologist would like to see for a heart image. Each thumbnail can be "clicked" by the mouse to initiate transfer of the entire FOV for that movie,

also in a few seconds. Importantly, this is achieved without loss of diagnostic information, without the need to adjust brightness/contrast, and without the need to adjust the frame rate of the movie. Step 4060 comprises adjusting other parameters, if warranted. When the physiologic knowledge engine **24** has completed these tasks on all images from a given patient, they are passed to the encoding engine **26**.

The encoding engine **26** (Fig. 8) is responsible for converting the images from the raw pixel format to a new format which can be displayed by browsers **14**. (Step 5010-5020.) One such format is the graphics interchange format (GIF), which can be used to display images in gray scale or color with or without animation (movies). The conversion is achieved using published definitions of web-compatible image formats and writing appropriate computer code. The images are then saved to disk and the post engine **28** is called.

The post engine **28** (Fig. 9) is responsible for generating the html pages within which the images will be displayed. (Steps 6010-6030.) These html pages may contain coding to display text such as the patient name, exam date, etc. (Step 6040.) In addition, the html page will contain html-standard image tags which instruct the browser **14** to display the converted images. The methods by which the html pages are constructed and the image tags embedded are standard to the Internet and are published elsewhere. The final responsibilities (Step 6050) of the post engine **28** are: 1) to transfer the completed html pages and the converted images to the Web-Compatible Database **32** (Figs. 2 and 3, details Fig. 10) located on the "http Server" **34** for viewing over the Internet; and 2) to send e-mail notification to the physician (or technician) via the e-mail server **30** (Fig. 2) stating that the images have been posted; and 3) providing the http

address for the images within the e-mail message such that the physician can "double-click" to immediately view the images.

Once the images are posted as web pages, additional web pages can be used to allow the technician or physician to rearrange the order of the images on the web page according to the diagnostic question. For example, echocardiographic images are often acquired before and after a drug to increase heart rate has been given (e.g., dobutamine). The images before and after the administration of dobutamine are best viewed side-by-side for comparison. Arranging the images side-by-side can be achieved by allowing the user to select images using html standard web page "forms." The form data can then be submitted using web-standard Common Gateway Interface (CGI) protocols and processed by the server using a CGI program written specifically for this purpose. The CGI program could then create a new web page in which the image containers are arranged side-by-side and the html "image tags" are set to point to the images defined by the user. Rearrangement of the images occurs very quickly because the images do not require further processing or transfer across the internet.

Fig. 11 shows how the Web-Compatible Database **32** of Fig. 10 can be used as the basic building block of a world-wide database which can be interrogated from any location on earth, for example, using any browser **14**. In practice, some form of security such as password protection would be provided to prevent unauthorized viewing of the image data.

As shown in Fig. 10, the database **32** is constructed as a hierarchical directory-tree with the patient's name **36** at a higher level than the modality **38**. Within each modality subdirectory, a series of directories with names corresponding to the scan date **40** would appear to allow for serial examinations over the patient's lifetime.

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The section of the URL “www.imagedatabase.com” refers to the company offering to serve the images over the Internet. Such a company would not process the images in any way because the images have already been processed as described herein. Rather, the sole function of such a company is to provide computing hardware which reads the “static” image data from a hard disk and pushes the data over the Internet (note that both still-frame images and movies are contained in “static” computer files). Because the images are already stored in the format of Internet web pages, no processing of the data is required resulting in maximum speeds for

image access and transfer and ensuring minimum cost for the overall system.

In fact, specialized computers which are capable of no function other than reading from a hard disk and pushing the data over the Internet already exist and could easily be assembled into a array of servers providing access to an extremely large amount of data over the Internet for minimum cost. For example, currently a commercial system of this type provides 120 GB of storage for \$3000. With 10 MB of image data per patient scan (typical), this system would provide permanent Internet access to 12,000 complete MRI patient scans for a cost of 25 cents each (exclusive of electrical and maintenance costs). Importantly, this type of world-wide database would be difficult if not impossible to construct if the processes described herein were not employed.

Fig. 12 shows how a user's request to view images (Step 7010) would be processed (Steps 7020-7040) by the world-wide database system of Fig. 11 using the basic building block of Fig. 10. Fig. 13 shows the resultant web page **40** displaying in response to a user sending a request to view "/Doe, John" via a browser **14**. Fig. 14 shows the result of clicking on "Cath" **42** (see Fig. 13) followed by clicking on the scan date (not shown). Identification data **43** is displayed with the image **44** corresponding to the examination data indicated. The html page **40'** and the embedded images **44** are sent by the http server **34** to the browser **14**. The images **44** can be still frames or movies depending on how they were originally acquired by the scanner **16**. In the case of movies, animated GIF format can be used by the encoding engine **26**. Figs. 15, 16, and 17 show the result of clicking on ECG, MRI, and SPECT, respectively. The time necessary to transfer the images **44** from the http Server **34** to the browser **14** will

depend on the size of the images **44** and the speed of the network, but was measured to be approximately 3 seconds for the entire set of MRI images of Fig. 16 over a standard ethernet 10BASET line (note that the top row of MRI images in Fig. 16 are movies displaying heart contraction).

Thus, using the current invention a database of images can be constructed with maximum Internet performance and without loss of diagnostic information. Importantly, the processes described herein allow viewing of images from multiple modalities side-by-side by the primary physician and/or the patient. Further, the database structure facilitates the storage of image data from multiple modalities and multiple scans over a patient's lifetime in a single location identified by the patient's name, social security number, or other unique identifier. This ability would be expected to significantly enhance the ability of the primary physician to determine the course of action which is in the best interest of the patient.

15 While the invention has been particularly shown and described with
reference to particular embodiments thereof, it will be understood by those
skilled in the art that various changes in form and detail may be made
therein without departing from the spirit and scope of the invention. The
scope of the claimed invention is intended to be defined by following claims
20 as they would be understood by one of ordinary skill in the art with
appropriate reference to the specification, including the drawings, as
warranted.